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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/578,849 05/26/2000 Michael Z. Martin 031727.0001A 7983

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HELLER EHRMAN WHITE & MCAULIFFE LLP
SUITE 300
101 ORCHARD RIDGE DR.
GAITHERSBURG, MD 20878-1917

EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/31/2001

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578,849

Applicant(s)

MARTIN ET AL.

Examiner

Francisco C Prats

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9-27-01; 11-20-01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 21-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-78 are pending.

Election/Restrictions

Applicant's election with traverse of the group II invention, claims 17-20, in Paper No. 8, filed September 27, 2001, is acknowledged. Applicant's election with traverse of the species wherein the volatile substance is methanol and wherein the natural source is kava root, in Paper No. 11, filed November 20, 2001, is also acknowledged.

The traversal is on the ground(s) that no serious burden warranting restriction between the various groups has been demonstrated. This is not found persuasive because the claims recite three different processes, each process having multiple steps, each process having differing steps. Further still, each of the processes recites a multitude of possible variants, using different solvents and/or starting materials and/or column media. In the elected invention for example, the process recites the use of 8 possible solvents or a combination thereof. Thus, the number of embodiments literally encompassed by that claim is eight factorial ($8! = 8 \times 7 \times 6 \times 5 \times 4 \times 3 \times 2 \times 1$) which is over 40,000 possible combinations. Moreover, each of the various groups contains similar alternative language and alternative

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embodiments literally yielding a multitude of possible inventive embodiments which must be searched. Further still, each of the various product claims contains numerous ingredients which are different from each other. Clearly examination of all claims presents a substantial burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-16 and 21-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8, filed September 27, 2001.

Claims 17-20 are examined on the merits to the extent they read on the elected species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Castor (U.S. Pat. 5,440,055).

Castor '055 discloses generally processes whereby taxol can be removed from extracts by chromatography in critical or near critical fluids. Castor '055 exemplifies a process whereby taxol is removed from an extract by chromatography in critical or near critical fluids including Freon-22, CO₂, methanol, methylene chloride, acetone, butanol and ethanol. See Examples 5 and 6, at columns 17 and 18. A holding of anticipation is clearly required.

Claims 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Castor (U.S. Pat. 5,750,709).

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Castor '709 discloses generally processes whereby therapeutic constituents present in natural sources can be purified by chromatography in supercritical, critical or near critical fluids. Castor '709 exemplifies a process whereby paclitaxol is removed from an extract by chromatography in critical fluids including Freon-22, CO₂, methanol, methylene chloride, acetone, butanol and ethanol. See Examples 5 and 6, at columns 19 and 20. A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35

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U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopez-Avila et al (J. High Resol. Chromatogr. 20:555-559 (1997)) and Schwabe (U.S. Pat. 5,296,224) in view of Castor (U.S. Pat. 5,440,055) and Castor (U.S. Pat. 5,750,709).

Each of Lopez-Avila and Schwabe disclose the preparation of extracts of kava root containing specific pharmacologically useful compounds, including kava lactones. See Lopez-Avila at abstract; see Schwabe '224 Examples 1-4, at cols. 3-7. Lopez-Avila and Schwabe differ from the claims in that neither reference uses supercritical, critical or near-critical chromatography as the separatory technique for extraction of the pharmacologically useful compounds.

However, both Castor '055 and '709 disclose that supercritical, critical or near-critical chromatography, using the claimed solvents including methanol, is a useful technique in recovering therapeutic compositions, such as taxols, from natural materials. See, e.g., Castor '709 at abstract. Disclosed advantages of the technique include improved production capacity, improved scalability, greater overall efficiency, fewer processing steps, and improved product quality. See Castor '709 at col. 7, lines 23-37. Note

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specifically that Castor '709 discloses that the techniques disclosed therein are applicable generally to virtually any biomass which potentially contains therapeutic materials. See Castor '709 at col. 4, lines 35-38.

Thus, the artisan of ordinary skill at the time of applicant's invention, seeking to prepare therapeutic compositions from kava root according to Lopez-Avila or Schwabe, would have been motivated by the Castor patents' disclosure of the advantages of supercritical, critical or near-critical chromatography to have employed supercritical, critical or near-critical chromatography to obtain therapeutic compositions and/or compounds from kava root. A holding of obviousness is therefore required.

Lastly, it is noted that none of the cited references discloses the specific column media recited in claim 19. However, the claimed chromatographic column media were well known in the art at the time of applicant's invention. Thus, the artisan of ordinary skill would clearly have considered the determination of a suitable column media for chromatographic purification of a particular compound or compounds to be a matter of selecting from among known equivalents recognized in the art to be useful in the processes disclosed in the Castor patents. Absent some evidence of an unexpected result inhering

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from the use of a particular chromatographic column medium, the use of known chromatographic media must be considered obvious.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
December 20, 2001